

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|   |   |  |                      |
|---|---|--|----------------------|
| Applicant's or agent's file reference<br>2003032-WO   | FOR FURTHER ACTION  |  | See Form PCT/PEA/416 |
| International application No.<br>PCT/DK2004/000677  | International filing date (day/month/year)<br>07.10.2004            | Priority date (day/month/year)<br>07.10.2003 |                      |
| International Patent Classification (IPC) or national classification and IPC<br>C08L39/06, C08L53/00, C09J139/06, C09J153/00, A61L24/00, A61L15/24  |   |  |                      |
| Applicant<br>COLOPLAST A/S et al.   |   |  |                      |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |   |  |                      |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>  |   |  |                      |
| Date of submission of the demand<br>27.04.2005  | Date of completion of this report<br>22.02.2006                     |  |                      |
| Name and mailing address of the international preliminary examining authority:<br><br><br>European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465  | Authorized Officer<br><br>Miao, K<br>Telephone No. +49 89 2399-8584 |  |                      |

INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY10/574916  
IAP9 Rec'd PCT/PTO 07 APR 2006  
International application No.  
PCT/DK2004/000677

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
    - international search (under Rules 12.3 and 23.1(b))
    - publication of the international application (under Rule 12.4)
    - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements\* of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

## Description, Pages

1-30 as originally filed

## Claims, Numbers

1-36 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3.  The amendments have resulted in the cancellation of:
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (specify):
  - any table(s) related to sequence listing (specify):

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (specify):
  - any table(s) related to sequence listing (specify):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**International application No.  
PCT/DK2004/000677**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

|                               |             |             |
|-------------------------------|-------------|-------------|
| Novelty (N)                   | Yes: Claims |             |
|                               | No: Claims  | 1-4,6,25,27 |
| Inventive step (IS)           | Yes: Claims |             |
|                               | No: Claims  | 1-4,6,25,27 |
| Industrial applicability (IA) | Yes: Claims | 1-36        |
|                               | No: Claims  |             |

**2. Citations and explanations (Rule 70.7):**

see separate sheet

**Box No. VII Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

see separate sheet

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following document/s/:

D1: US 5 846 214 A (ISOBE KAZUKI ET AL)

8 December 1998 (1998-12-08)

D2 US 6 303 700 B1 (CHEN FEI)

16 October 2001 (2001-10-16)

D3 US 6 024 976 A (MIRANDA JESUS ET AL)

15 February 2000 (2000-02-15)

D4 US 6 221 383 B1 (MIRANDA JESUS ET AL)

24 April 2001 (2001-04-24)

D5 WO 03/020824 A (BEIERSDORF AG ; NIERLE

JENS (DE); WOELLER KARL-HEINZ (DE))

13 March 2003 (2003-03-13)

1. The subject-matter of claims 1-4, 6, 25 and 27 is not novel (Art. 33(2) PCT) over D1.

1.1 Claims 10-12 and 14 of D1 are relevant.

2. The applicant has not provided convincing arguments as to why SIS is not an amphiphilic block copolymer as defined in present claim 1.

The mention of such a feature is, in itself, broad and does not limit it to SIS unless the applicant can demonstrate to the contrary.

3. In any case, inventive step (Art. 33(3) PCT) cannot be given to said claims, since it is not obvious what the advantages of an amphiphilic block copolymer provides to the subject-matter.

**Re Item VII**

**INTERNATIONAL PRELIMINARY  
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(SEPARATE SHEET)**

International application No.

PCT/DK2004/000677

**Certain defects in the international application**

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1 as well as D2-4 and D5 has neither been mentioned nor identified in the description.

**Re Item VIII**

**Certain observations on the international application**

The following deficiencies (Art. 6 PCT) have not been overcome :

1. The support for claims 23-36 is not clear from the description.
2. The feature "...intrinsic adhesive properties." in claims 2-3 and 5 are vague and should be avoided.
  - 2.1. In this connection, what "...adhesive properties..." are being referred to in claim 5 ?
3. Separate dependent claims should be drawn up for preferred embodiments (see claims 6 and 9-10).
4. The feature "...suitable PEG 400..." in claim 8 should be explained, if not *for the file only*.

Such a feature in claim 8 is not allowable.

5. The blocks A and B in claim 11 have not been defined.
6. The phrase "...such as..." and the term "..., e.g.", especially in the claims should be suitably replaced without the violation of Art. 6 PCT.
  - 6.1. Likewise, the phrase "...adapted for being attached..." in claim 26 should be suitably replaced.
  - 6.2. Moreover, the feature "...in an amount sufficient to achieve a slippery surface..." in claim 32 is, also, vague and should be suitably replaced.
  - 6.3. Words such as "...improving..." in the claims should, also, be avoided.

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(SEPARATE SHEET)**

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7. What is meant by **osmolality** in claim 33 ?
8. It is unclear whether all the essential features of the independent claim have been fully exemplified.

An explanation would be deemed appropriate *for the file only*, since any amendments to the worked examples are in violation to Art. 34(2)(b) PCT.

9. Registered Trade Marks should be acknowledged throughout the application.
10. Clerical and typographical errors should be removed from the application.

Please be informed that the Examiner in Charge of the International Preliminary Examination may not carry out any amendments in the application even if requested to do so. Amendments should be filed on retyped pages (Rule 11.9 PCT), which are necessary for legibility and clarity reasons.

If amendments are carried out, the reply should indicate in detail (e.g. in the form of a list), where (page / line) these amendments find their support in the application as originally filed (PCT Guidelines Chapter VI, paragraphs 7.1-7.4) in order to verify that the requirements of Art. 34(2)(b) PCT have been fulfilled.

Additionally, the Applicant is requested to clearly point out on one of the new copies of the original pages, which amendments have been made (PCT Guidelines VI, paragraphs 7.1-7.4).

Any information the Applicant may wish to submit concerning the subject-matter of the invention, for example, further details of its advantages or problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply rather than be incorporated into the application (Art. 34(b) PCT).